FDA-Industry PDUFA V Reauthorization Meeting
Financial Sub-Group
January 18, 2011, 8:30am-9:45am
Teleconference

Purpose
To continue discussion of FDA technical proposals and the PDUFA Inflation Adjuster.

Participants

FDA		Industry	
Daniel Brounstein	CDER	Tom Dilenge	BIO
Donal Parks	CDER	Andrew Emmett	BIO
Theresa Mullin	CDER	Sascha Haverfield	PhRMA
		Mark Mayer	Lilly
		Bob Meyer	Merck

Technical Proposals Discussion

FDA continued discussion of the Expiration Date and Discontinued Products technical proposals provided to Industry. FDA noted that the changes FDA made to the previous language were reviewed internally by FDA's chief counsel and deemed to be straightforward. Industry and FDA agreed that the Industry responses should be provided by the middle to end of this week.

In a continuation of discussion of the Small Business Waiver proposal, FDA and Industry agreed to schedule a teleconference, to include legal counsel from the respective parties, to discuss the proposed definition of the term "affiliate."

FDA Inflation Adjuster Presentation

FDA discussed the current PDUFA Inflation Adjuster and the degree to which FDA Payroll Compensation and Benefit (PC&B) costs (one of the current statutory bases for adjustment) can serve as a reasonable proxy for non-payroll costs such as Contracts Services. FDA expressed concern that the use of a national index, such as the Consumer Price Index, might be a poor proxy of the escalation in agency costs and would result in adjustments that fail to keep pace with costs, leading to reduced FDA capacity to perform the human drug review process.

Industry questioned whether FDA was discussing inflation adjustment or cost adjustment. FDA responded that the current statutory provisions allow for three alternative Inflation Adjuster measures that each address FDA's cost inflation—that is escalation in program costs that are outside of the Agency's control. In terms of senior scientific review staff payroll and benefits, the largest cost category where policies are determined by federal government directives and regulations, FDA added that there is nothing that captures these cost trends as well as PC&B does directly.

Industry requested that an Inflation Adjuster be created that takes multiple indices into account and measures how those inflation pressures develop over time. FDA stated that use of a composite of more than one metric might be helpful, but too many metrics would create an overly-complex, difficult to operate system. Industry also stated that they would like the inflation adjuster to be more responsive to changes in cost factors and therefore wanted to consider an adjuster based on less than the current 5 year rolling average for PDUFA V.

Baseline Costs Per FTE

FDA reviewed the estimated cost per review FTE as one of the action items previously identified, and noted that the earlier-projected $300,000 per FTE projected for FY2013 is likely to be higher than what is now expected based on the more recently instituted federal pay freeze. FDA proposed using the FDA average cost per FTE, projected to be $294,000 per FTE. Industry responded that they will take this estimate to their stakeholders for further discussion.

FDA-Industry PDUFA V Reauthorization Meeting
Ad-hoc Sub-Group
January 18, 2011, 3:30-4:30pm
Teleconference

Purpose

To discuss the proposal to improve human subject protection in clinical trial oversight

Participants

FDA		Industry	
Leslie Ball	CDER	Annetta Beauregard	EMD Serono
Rachel Behrman	CDER	Andrew Emmett	BIO
Patrick Frey	CDER	Jeffrey Francer	PhRMA
Ann Meeker-O'Connell	CDER	Sascha Haverfield	PhRMA
Theresa Mullin	CDER	Helen Thackray	Glycomimetics

FDA discussed its revisions to the proposal for a quality systems approach to clinical trial oversight in PDUFA V. This proposal is designed to shift clinical trial oversight to an approach that identifies risks to data quality and integrity and human subject protection before clinical trials begin and develops strategies to monitor and mitigate those risks during the trials. The revisions to the proposal were based on feedback from Industry at the January 6, 2011, meeting of the sub-group. Industry agreed that a quality systems approach is the right direction for clinical trial oversight; however, Industry stated its concern that a new approach should be fully integrated into the review process. Industry also requested clarification on whether this alternative approach would be an additional approach to oversight or a replacement for the current approach in the human drug review process, which relies on site inspections after the clinical trial has been completed.

Industry also questioned the appropriateness of this proposal in the context of PDUFA discussions. FDA stated that the agency's clinical trial oversight responsibilities are a part of the human drug review process that is partially funded by PDUFA. The agency stated that a quality systems approach to oversight has already been endorsed by some in Industry, because of the focus on problem prevention, and that a movement toward this approach is already happening, albeit at a slow pace due to resource constraints. FDA stated that additional resources in PDUFA V would provide the catalyst for more rapid uptake and a shift away from the current inspection approach during the human drug review process.

Industry requested that FDA describe how a quality team would interact with existing staff responsible for clinical trial oversight, what a quality plan would look like, what the pilot program would look like, how the pilot could be used to shift away from the current inspectional approach during the human drug review process, how knowledge gained from the pilot would be distributed, and how this new approach would be integrated into the review process. Industry also requested that a future revision of this proposal include more clarity on the link from the proposal to a new inspection regime and how quality plans and real-time inspections would fit into clinical trial oversight. FDA agreed to provide additional detail in the next proposal revision, although the agency noted that the level of detail Industry requested of the pilot program might require the program to have already been completed.